

IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: John F. Engelhardt et al.

Title: COMPOUNDS AND METHODS TO ENHANCE rAAV TRANSDUCTION

Docket No.: 875.074US1

Serial No.: 10/815,262

Filed: March 31, 2004

Due Date: N/A

Examiner: Unknown

Group Art Unit: 1636

MS Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

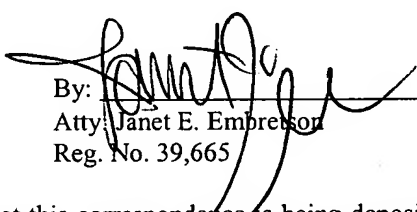
☒ Return postcard.

☒ Supplemental Information Disclosure Statement (2 pgs.), Form 1449 (4 pgs.), and copies of 40 cited documents.

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

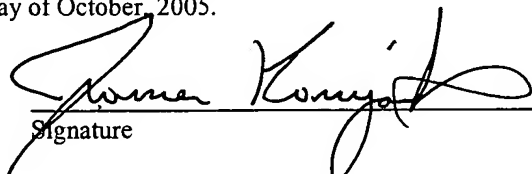
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

Customer Number 21186

By: 
Atty: Janet E. Emberson
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 3rd day of October, 2005.


Name


Signature

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

(GENERAL)

S/N 10/815,262



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	John F. Engelhardt et al.	Examiner:	Unknown
Serial No.:	10/815,262	Group Art Unit:	1636
Filed:	March 31, 2004	Docket:	875.074US1
Title:	COMPOUNDS AND METHODS TO ENHANCE rAAV TRANSDUCTION		

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicant respectfully requests that this Supplemental Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicant requests that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicant with the next official communication.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Supplemental Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 19-0743 in order to have this Supplemental Information Disclosure Statement considered.

Pursuant to 37 C.F.R. 1.98(a)(2), Applicant believes that copies of cited U.S. Patents and Published Applications are no longer required to be provided to the Office. Notification of this change was provided in the United States Patent and Trademark Office OG Notices dated October 12, 2004. Thus, Applicant has not included a copy of the Published Application cited with this submission. Should the Office require copies to be provided, Applicant respectfully requests that notice of such requirement be directed to Applicant's below-signed representative. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

The Examiner is invited to contact the Applicant's Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

JOHN F. ENGELHARDT ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6959

Date OCTOBER 3, 2005 By [Signature]
Janet E. Embretson
Reg. No. 39,665

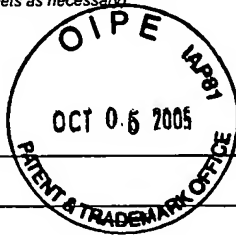
CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 3RD day of October, 2005.

JAMES KANYUSIK
Name

[Signature]
Signature

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO
**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Use as many sheets as necessary)



Sheet 1 of 4

Complete if Known

Application Number	10/815,262
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1636
Examiner Name	Unknown

Attorney Docket No: 875.074US1

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Filing Date If Appropriate
	US-2003/0103939 A1	06/05/2003	Engelhardt, J. E., et al.	07/12/2002

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		BANK, U., "Review: Peptidases and Peptidase Inhibitors in the Pathogenesis of Diseases", <u>Cellular Peptidases in Immune Functions and Diseases 2</u> , (Edited by Jurgen Langner, et al., Kluwer Academic / Plenum Publishers), (2000), 349-378	
		BRÖTZ, H., "The Lantibiotic Mersacidin Inhibits Peptidoglycan Biosynthesis and the Level of Transglycosylation", <u>Eur. J. Biochem.</u> , 246(1), (1997), 193-199	
		CONRAD, C. K., et al., "Safety of Single-Dose Administration of an Adeno-Associated Virus (AAV)-CFTR Vector in the Primate Lung", <u>Gene Therapy</u> , 3(8), (August 1996), 658-668	
		CROYLE, M., et al., "Development of Novel Formulations that Enhance Adenoviral-Mediated Gene Expression in the Lung <i>in Vitro</i> and <i>in Vivo</i> ", <u>Molecular Therapy</u> , 4(1), (2001), 22-28	
		DING, W., et al., "Second-Strand Genome Conversion of Adeno-Associated Virus Type 2 (AAV-2) and AAV-5 is Not Rate Limiting Following Apical Infection of Polarized Human Airway Epithelia", <u>Journal of Virology</u> , 77(13), (2003), 7361-7366	
		DISHART, K., et al., "Recombinant Adeno-Associated Virus-2 as a Candidate Gene Delivery Vector for Vein Grafts", <u>American Society of Gene Therapy, Abstracts of Scientific Presentations (Abstract No. 1107)</u> , (2002), 1 pg.	
		DONALDSON, S. H., et al., "Regulation of the Epithelial Sodium Channel by Serine Proteases in Human Airways", <u>The Journal of Biological Chemistry</u> , 277(10), (2002), 8338-8345	
		DOUAR, A.-M., et al., "Intracellular Trafficking of Adeno-Associated Virus Vectors: Routing to the Late Endosomal Compartment and Proteasome Degradation", <u>Journal of Virology</u> , 75(4), (2001), 1824-1833	
		DUAN, D., et al., "A New Dual-Vector Approach to Enhance Recombinant Adeno-Associated Virus-Mediated Gene Expression Through Intermolecular cis Activation", <u>Nature Medicine</u> , 6(5), (2000), 595-598	
		DUAN, D., et al., "Chapter 15: <i>Trans</i> -Splicing Vectors Expand the Packaging Limits of Adeno-Associated Virus for Gene Therapy Applications", <u>Methods in Molecular Medicine, Vol. 76: Viral Vectors for Gene Therapy: Methods and Protocols</u> , (2003), 287-307	
		DUAN, D., et al., "Chapter 3 - Adeno-Associated Virus", In: <u>Lung Biology in Health and Disease, Vol. 169 - Gene Therapy in Lung Disease</u> , Albelda, S. M., Editor, Marcel Dekker, Inc., (2002), 51-92	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional) ² Applicant is to place a check mark here if English language Translation is attached

Substitute for form 1449A/PTO
**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Use as many sheets as necessary)

Complete if Known

Application Number	10/815,262
Filing Date	March 31, 2004
First Named Inventor	Engelhardt, John
Group Art Unit	1636
Examiner Name	Unknown

Sheet 2 of 4

Attorney Docket No: 875.074US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		DUAN, D. , et al., "Chapter 3 - Dual Vector Expansion of the Recombinant AAV Packaging Capacity", In: <u>Methods in Molecular Biology</u> , Vol. 219: <u>Cardiac Cell and Gene Transfer</u> , Metzger, J. M., Editor, Human Press, Inc., Totowa, NJ,(2003),29-51	
		DUAN, D. , et al., "Consequences of DNA-Dependent Protein Kinase Catalytic Subunit Deficiency on Recombinant Adeno-Associated Virus Genome Circularization and Heterodimerization in Muscle Tissue", <u>Journal of Virology</u> , 77(8), (2003),4751-4759	
		DUAN, D., et al., "Enhancement of Muscle Gene Delivery With Pseudotyped Adeno-Associated Virus Type 5 Correlates With Myoblast Differentiation", <u>Journal of Virology</u> , 75(16), (2001),7662-7671	
		DUAN, D. , et al., "Expanding AAV Packaging Capacity With <i>Trans</i> -splicing or Overlapping Vectors: A Quantitative Comparison", <u>Molecular Therapy</u> , 4(4), (2001),383-391	
		ENGELHARDT, J. F., et al., "Direct Gene Transfer of Human CFTR Into Human Bronchial Epithelia of Xenografts With E1-Deleted Adenoviruses", <u>Nature Genetics</u> , 4, (1993),27-34	
		ENGELHARDT, J. F., "The Lung as a Metabolic Factory for Gene Therapy", <u>The Journal of Clinical Investigation</u> , 110(4), (2002),429-432	
		FLOTTE, T. R., et al., "Adeno-Associated Virus Vector Gene Expression Occurs in Nondividing Cells in the Absence of Vector DNA Integration", <u>American Journal of Respiratory Cell and Molecular Biology</u> , 11, (1994), 517-521	
		FLOTTE, T. R., et al., "Chapter 40 - Adeno-Associated Viral Vectors for CF Gene Therapy", In: <u>Methods in Molecular Medicine</u> , 70, (2002),599-608	
		GRUCHALA, M., et al., "Adeno-Associated Virus-Mediated Gene Transfer into Normal Rabbit Arteries. Assessment of the Tie and CMV Promoters and the Antiproteasome Treatment with MG-132", <u>American Society of Gene Therapy</u> , Abstracts of Scientific Presentations -abstract no. 1110,(June 5, 2002),1 page	
		HANSEN, J. , et al., "Adeno-Associated Virus Type 2-Mediated Gene Transfer: Altered Endocytic Processing Enhances Transduction Efficiency in Murine Fibroblasts", <u>Journal of Virology</u> , 75(9), (2001),4080-4090	
		HANSEN, J. , et al., "Impaired Intracellular Trafficking of Adeno-Associated Virus Type 2 Vectors Limits Efficient Transduction of Murine Fibroblasts", <u>Journal of Virology</u> , 74(2), (2000),992-996	
		HOSSEINI, H., et al., "Protection Against Experimental Autoimmune Encephalomyelitis by a Proteasome Modulator", <u>Journal of Neuroimmunology</u> , 188, (2001),233-244	
		ITANI, O. A., et al., "Cycloheximide Increases Glucocorticoid-Stimulated α -ENaC mRNA in Collecting Duct Cells by p38 MAPK-dependent Pathway", <u>Am. J. Physiol. Renal Physiol.</u> , 284, (2002),F778-F787	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="padding: 2px;"><i>Complete if Known</i></td> </tr> <tr> <td style="width: 60%; padding: 2px;">Application Number</td> <td style="padding: 2px;">10/815,262</td> </tr> <tr> <td style="padding: 2px;">Filing Date</td> <td style="padding: 2px;">March 31, 2004</td> </tr> <tr> <td style="padding: 2px;">First Named Inventor</td> <td style="padding: 2px;">Engelhardt, John</td> </tr> <tr> <td style="padding: 2px;">Group Art Unit</td> <td style="padding: 2px;">1636</td> </tr> <tr> <td style="padding: 2px;">Examiner Name</td> <td style="padding: 2px;">Unknown</td> </tr> </table>	<i>Complete if Known</i>		Application Number	10/815,262	Filing Date	March 31, 2004	First Named Inventor	Engelhardt, John	Group Art Unit	1636	Examiner Name	Unknown
<i>Complete if Known</i>													
Application Number	10/815,262												
Filing Date	March 31, 2004												
First Named Inventor	Engelhardt, John												
Group Art Unit	1636												
Examiner Name	Unknown												
Sheet 3 of 4	Attorney Docket No: 875.074US1												

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T. ²
		KIYOMIYA, K.-I., et al., "Mechanism of Specific Nuclear Transport of Adriamycin: The Mode of Nuclear Translocation of Adriamycin-Proteasome Complex", <u>Cancer Research</u> , (2001),2467-2471	
		MATTSSON, K., et al., "Proteins Associated With the Promyelocytic Leukemia Gene Product (PML)-Containing Nuclear Body Move to the Nucleolus Upon Inhibition of Proteasome-Dependent Protein Degradation", <u>Proc. National Academy of Science</u> , 98(3), (2001),1012-1017	
		MCAULIFFE, O., et al., "Lantibiotics: Structure, Biosynthesis and Mode of Action", <u>FEMS Microbiology Reviews</u> , 25(3), (2001),285-308	
		NIELSEN, J., et al., "Spironolactone-Mediated Downregulation of the Epithelial Sodium Channel (eNaC) in Rat Kidney", <u>FASEB Journal</u> , 15(1) (Abstracts Part I), (Abstract No. 393.11), (2001), A432	
		PARKER, J. S., et al., "Cellular Uptake and Infection by Canine Parvovirus Involves Rapid Dynamin-Regulated Clathrin-Mediated Endocytosis, Followed by Slower Intracellular Trafficking", <u>Journal of Virology</u> , 74(4), (2000),1919-1930	
		SANLIOGLU, S. , et al., "Endocytosis and Nuclear Trafficking of Adeno-Associated Virus Type 2 Are Controlled by Rac1 and Phosphatidylinositol-3 Kinase Activation", <u>Journal of Virology</u> , 74(19), (2000),9184-9196	
		SANLIOGLU, S. , et al., "Lipopolysaccharide Induces Rac1-Dependent Reactive Oxygen Species Formation and Coordinates Tumor Necrosis Factor- α Secretion Through IKK Regulation of NF- κ B", <u>The Journal of Biological Chemistry</u> , 276(32), (2001),30188-30198	
		SANLIOGLU, S. , et al., "Loss of ATM Function Enhances Recombinant Adeno-Associated Virus Transduction and Integration Through Pathways Similar to UV Irradiation", <u>Virology</u> , 268, (2000),68-78	
		SANLIOGLU, S. , et al., "Rate Limiting Steps of AAV Transduction and Implications for Human Gene Therapy", <u>Current Gene Therapy</u> , 1, (2001),137-147	
		SANLIOGLU, S. , et al., "Two Independent Molecular Pathways for Recombinant Adeno-Associated Virus Genome Conversion Occur After UV-C and E4orf6 Augmentation of Transduction", <u>Human Gene Therapy</u> , 10(4), (1999),591-602	
		SASAKI, T. , et al., "Inhibitory Effect of di- and Tripeptidyl Aldehydes on Calpains and Cathepsins", <u>Journal of Enzyme Inhibition</u> , 3(3), (1990),195-201	
		STAUB, O., "Chapter 5 Regulation of ENaC by Interacting Proteins and by Ubiquitination", <u>Current Topics in Membranes</u> , 47 - <u>Amiloride-Sensitive Sodium Channels - Physiology and Functional Diversity</u> , Edited by Dale J. Benos, Academic Press, Publisher, (1999),65-87	
		STAUB, O., "Regulation of Stability and Function of the Epithelial Na ⁺ Channel (ENaC) by Ubiquitination", <u>The EMBO Journal</u> , 16(21), (1997),6325-6336	

EXAMINER

DATE CONSIDERED

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>	Complete if Known <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Application Number</td> <td>10/815,262</td> </tr> <tr> <td>Filing Date</td> <td>March 31, 2004</td> </tr> <tr> <td>First Named Inventor</td> <td>Engelhardt, John</td> </tr> <tr> <td>Group Art Unit</td> <td>1636</td> </tr> <tr> <td>Examiner Name</td> <td>Unknown</td> </tr> </table>	Application Number	10/815,262	Filing Date	March 31, 2004	First Named Inventor	Engelhardt, John	Group Art Unit	1636	Examiner Name	Unknown
Application Number	10/815,262										
Filing Date	March 31, 2004										
First Named Inventor	Engelhardt, John										
Group Art Unit	1636										
Examiner Name	Unknown										
Sheet 4 of 4	Attorney Docket No: 875.074US1										

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		STOCKAND, J. D., et al., "Targeted Degradation of the Epithelial Na Channel (ENaC) in Response to PKC Activation of the MAPK 1/2 Cascade", <u>The FASEB Journal</u> , 17(5), Abstracts (Part II), (Abstract No. 585.7), (2003), A913	
		STOKES, J. B., "Regulation of rENaC mRNA by Dietary NaCl and Steroids: Organ, Tissue, and Steroid Heterogeneity", <u>American Journal of Physiology, Cell Physiology</u> , 274, (1998), C1699-C1707	
		YAN, Z., et al., "[20] Recombinant AAV-Mediated Gene Delivery Using Dual Vector Heterodimerization", In: <u>Methods in Enzymology</u> , Vol. 346: <u>Gene Therapy Methods</u> , Phillips, M. I., Editor, Academic Press, San Diego, CA, (2002), 334-357	

EXAMINER

DATE CONSIDERED